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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,406	04/11/2001	Ronald Erwin Boch	273012011300	3418

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 03/28/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/833,406

Applicant(s)
Boch

Examiner
Gollamudi Kishore

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 22, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21, 23-36, 39, and 41 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21, 23-36, 39, and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11 6) ☐ Other:

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DETAILED ACTION

The request for the extension of time and amendment filed on 2-22-03 are acknowledged.

Claims included in the prosecution are 21, 23-36, 39 and 41.

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 2. Claims 21, 23-36, 39 and 41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The negative limitations, ‘unsaturated phospholipid is not egg phosphatidylglycerol’ in claims 21 and 40, ‘do not comprise egg phospholipid’ in claim 30, ‘unsaturated phospholipid is not egg phosphatidylglycerol’ in claim 32, do not have support in the specification as originally filed and therefore, deemed to be new matter .**

Applicant’s arguments have been fully considered, but are not found to be persuasive. Applicant argues that the specification discloses the whole of unsaturated

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phosphatidylglycerols as a genus and then details a number of species, including EPG, within the genus. This argument is not found to be persuasive since 1) the genus in the claims is not just phosphatidylglycerol, but 'phospholipid'; 2) specification on page 28 just lists three phosphatidylglycerols two of which are synthetic and the third is egg phosphatidylglycerol. Furthermore, in claim 21, applicant excludes phosphatidylglycerol and in the dependent claim 30 applicant excludes even the genus, 'egg phospholipids' which is confusing.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The parent claim 21 is now amended to recite micelles; however, the dependent claim 30 still recite 'lipid bilayers'; this is inconsistent with the parent claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 21, 23-25, 29, 32-33 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Madden (5,389,378).

Madden discloses liposome formulations containing BPD-MA, DMPC (saturated lipid) and PC (unsaturated lipid). The method of preparation involves the mixing the agents and the lipids, evaporation of the solvent and hydrating the film at 30 degrees (note the abstract, columns 5-8, Examples and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the claims have been amended to recite micellar formulations and Madden does not teach micellar formulations. This argument is not found to be persuasive since the method of preparation is the same in both prior art and in instant invention. It is noted from the specification on page 28, 1st paragraph where applicant states that "phospholipids used are those capable of forming liposomes, but also are able to result in the production of micelles if a high energy processing step is used for size reduction of multilamellar liposomes and the prior art uses high energy processing. The examiner cites in this context, the reference of Wan which discloses that phospholipids are amphiphilic in nature and have a propensity to form micelles and bilayers in an aqueous medium Col. 2, lines 3-5). Furthermore, instant claim language 'comprising' does not exclude liposomes which are also present in the prior art compositions.

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7. **Claims 21, 23-24, 27-29, 32-33, 35-36, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu (5,707,608) or Desai (6,074,666) both are of record.**

Liu discloses liposome formulations containing the claimed green porphyrins, DMPC and PG. The compositions include an antioxidant. The method of preparation involves the mixing the agents and the lipids, evaporation of the solvent and hydrating the film below 30 degrees (note the abstract, columns 6-12, Examples and claims).

Similarly, Desai discloses liposome formulations containing the claimed green porphyrins, DMPC and PG. The compositions include an antioxidant. The method of preparation involves the mixing the agents and the lipids, evaporation of the solvent and hydrating the film below 30 degrees (note the abstract, columns 3-7, Examples and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the claims have been amended to recite micellar formulations and neither Liu nor Desai teach micellar formulations. This argument is not found to be persuasive since the method of preparation is the same in both prior art and in instant invention. It is noted from the specification on page 28, 1st paragraph where applicant states that "phospholipids used are those capable of forming liposomes, but also are able to result in the production of micelles if a high energy processing step is used for size reduction of multilamellar liposomes and the prior art uses high energy processing. The examiner once again points to the reference of Wan which discloses that phospholipids

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are amphiphilic in nature and have a propensity to form micelles and bilayers in an aqueous medium Col. 2, lines 3-5). Furthermore, as pointed out above, instant claim language 'comprising' does not exclude liposomes which are also present in the prior art compositions.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 21, 23-36, 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madden or Liu or Desai cited above by themselves, or further in view of Young (6,375,930) and Wan (5,329,029).

As discussed above,

Madden discloses liposome formulations containing BPD-MA, DMPC (saturated lipid) and PC (unsaturated lipid). The method of preparation involves the mixing the agents and the lipids, evaporation of the solvent and hydrating the film at 30 degrees (note the abstract, columns 5-8, Examples and claims).

Liu discloses liposome formulations containing the claimed green porphyrins, DMPC and PG. The compositions include an antioxidant. The method of preparation

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involves the mixing the agents and the lipids, evaporation of the solvent and hydrating the film below 30 degrees (note the abstract, columns 6-12, Examples and claims).

Similarly, Desai discloses liposome formulations containing the claimed green porphyrins, DMPC and PG. The compositions include an antioxidant. The method of preparation involves the mixing the agents and the lipids, evaporation of the solvent and hydrating the film below 30 degrees (note the abstract, columns 3-7, Examples and claims).

What is lacking in Madden, Liu, and Desai are the explicit teachings of micellar formulations containing phospholipids. Applicant on page 28 of the specification indicate that hydration to multilamellar vesicles followed by high energy processing step would result in the formation of micelles. Since the references teach the high energy processing steps, it would have been obvious to one of ordinary skill in the art that the compositions in the prior art would also contain micelles besides liposomes. It would appear that the references do not teach claimed porphyrin derivatives. Applicants in the specification indicate that the claimed derivatives are known in the art. The use of art known porphyrins in the liposomes of Madden or Liu or Desai, with the expectation of obtaining at least similar results, would have been obvious to one of ordinary skill in the art since these are photosensitizers with the same basic porphyrin structure.

Young discloses that photodynamic therapy could be practiced with photosensitizing material in carriers such as micelles and liposomes (abstract, col. 11, line

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33 through col. 13, line 43). Although Young discusses phospholipids, it is unclear whether he specifically advocates their use in the micelle formation.

Wan discloses that phospholipids are amphiphilic in nature and have a propensity to form micelles and bilayers in an aqueous medium Col. 2, lines 3-5).

The use of phospholipids as micellar forming structures in Lentini, and Young would have been obvious to one of ordinary skill in the art since phospholipids are known active agent carriers and the reference of Wan shows that they have the ability to form either liposomes or micelles upon the addition of an aqueous medium.

10. Claims 21, 23-36, 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Lentini (5,885,557) or Young (6,375,930) in further combination with either Desai (6,074,666) or Madden (5,389,378).

Lentini, and Young both disclose that photodynamic therapy could be practiced with photosensitizing material in carriers such as micelles and liposomes (note the abstract, col. 7, line 62 through col. 8, line 29 of Lentini; abstract, col. 11, line 33 through col. 13, line 43). What is lacking in Lentini is the teaching of the compounds making up the micelles. Although Young discusses phospholipids, it is unclear whether he specifically advocates their use in the micelle formation.

Wan discloses that phospholipids are amphiphilic in nature and have a propensity to form micelles and bilayers in an aqueous medium Col. 2, lines 3-5).

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The use of phospholipids as micellar forming structures in Lentini, and Young would have been obvious to one of ordinary skill in the art since phospholipids are known active agent carriers and the reference of Wan shows that they have the ability to form either liposomes or micelles upon the addition of an aqueous medium.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

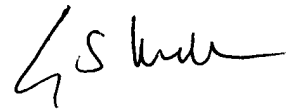
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

A handwritten signature in black ink, appearing to read 'G S Kishore'.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

March 26, 2003